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EXAMINER

STRZELECKA, TERESA E

ART UNIT PAPER NUMBER

1637

DATE MAILED: 02 21 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/616,526

Applicant(s)

ABDUL MALAK ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 and 50-58 is/are pending in the application.
- 4a) Of the above claim(s) 50-52 and 55-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-45) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that claims of Groups III (claims 48 and 49, replaced by claims 55-58) and Group IV (claims 50-52) are related to elected Group I claims by a single inventive concept. This is not found persuasive because Group I claims are drawn to a composite collagen material and its method of making, whereas methods of Group III are drawn to using artificial skin for in vitro testing of materials, and claims of Group IV are drawn to using the artificial skin for reconstructing damaged skin. As these methods can be practiced with different materials, such as cell culture or skin grafts, they are considered as separate inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 50-52 and 55-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-41, 44, 45, 53 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1, 9, 12, 13, 20 and 21 are indefinite because of the limitation "...essentially compact collagen membrane...". It is unclear what properties of the membrane are described by this term.

B) Claim 2 is indefinite because of the limitation "...fluid selected from air and gaseous fluid...". It is unclear what substances belong to this category.

C) Claim 2 is indefinite due to the improper expression of alternative limitations.

"Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being 'selected from the group consisting of A, B, and C'." (MPEP 2173.05(d)). To overcome this rejection, the claim may be amended to recite "selected from the group consisting of" in line 2 where it now recites "selected from".

D) Claim 3 is indefinite due to the improper expression of alternative limitations.

"Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being 'selected from the group consisting of A, B, and C'." (MPEP 2173.05(d)). To overcome this rejection, the claim may be amended to recite "selected from the group consisting of" in line 2 where it now recites "selected from".

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E) Claim 4 is indefinite due to the improper expression of alternative limitations.

“Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being ‘selected from the group consisting of A, B, and C’.” (MPEP 2173.05(d). To overcome this rejection, the claim may be amended to recite “selected from the group consisting of” in line 1 where it now recites “selected from”.

F) Claims 6 and 36 are indefinite because of the limitation “...cells are originating substantially exclusively from young subjects...”. It is unclear what the term “originating substantially exclusively means”. In addition, more proper English usage would be “cells originate” rather than “cells are originating”.

G) Claims 7 and 37 are indefinite because of the limitation “...cells are originating substantially exclusively from elderly subjects...”. It is unclear what the term “originating substantially exclusively means”. In addition, more proper English usage would be “cells originate” rather than “cells are originating”.

H) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required,

or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 8 and 38 recite the broad recitation "blood cells", and the claims also recite "particularly macrophages or lymphocytes" which is the narrower statement of the range/limitation.

I) Claim 9 is indefinite due to the improper expression of alternative limitations.

"Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being 'selected from the group consisting of A, B, and C'." (MPEP 2173.05(d). To overcome this rejection, the claim may be amended to recite "selected from the group consisting of" in line 3 where it now recites "selected from".

J) Claims 16, 19, 28 and 34 recite the limitation "one of the two layers" in line 1. There is insufficient antecedent basis for this limitation in the claims.

K) Claim 20 is indefinite because it does not contain active method steps. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See *Ex parte Erlich*, 3 USPQ2d, p. 1011 (Bd. Pat. App. Int. 1986). It is suggested that the claims be rewritten such that they set forth defined methods, such as by reciting "[a] method of..., comprising the steps of ...", after which a series of active steps is recited, for example "obtaining a biological sample" or "hybridizing a probe to said biological sample, wherein said probe...".

L) Claim 25 is indefinite due to the improper expression of alternative limitations.

"Alternative expressions are permitted if they present no uncertainty or ambiguity with

respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being 'selected from the group consisting of A, B, and C.'" (MPEP 2173.05(d). To overcome this rejection, the claim may be amended to recite "selected from the group consisting of" in line 3 where it now recites "selected from".

M) Claim 34 is indefinite because of the limitation "...concomitant culture...". It is unclear what this term means.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8, 10-20, 23-38, 40, 41, 42, 44, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce (U.S. Patent No. 5,273,900).

Claims 10 and 11 were included in the product claim rejection as it is not clear what special properties are imparted to the composite by compression under pressure.

Boyce teaches a composite skin replacement comprising two components: an epidermal component and a porous, laminated dermal membrane. The dermal membrane is prepared from bovine collagen and a glycosaminoglycan (GAG), a polysaccharide. The membrane is covered with a laminating layer containing a mixture of collagen and GAG (Abstract; col. 7, lines 7-16). The dermal membrane is then covered with normal keratinocytes (col. 7, lines 17-39).

To prepare the membrane, the membrane solution is frozen, lyophilized and cross-linked by physical or chemical means. Then a separately prepared gel of collagen and GAG is deposited onto the membrane, the two layers are frozen and lyophilized, then cross-linked using high temperatures and a vacuum or UV light. The laminated dermal membrane is then rehydrated and cross-linked with glutaraldehyde (col. 7, lines 40-62; col. 9, lines 17-66). Freezing is conducted in the freezing bath containing isopropanol or by using liquefied gases such as nitrogen, propane or air (col. 9, lines 25-36).

The dermal layer may be modified by an addition of biologically active molecules such as growth factors (col. 10, lines 1-5). The normal human keratinocytes are then inoculated into the dermal membrane, forming epidermal layer on the membrane's surface (col. 10, lines 45-54; col. 16, lines 26-32).

8. Claims 9, 43, 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisenberg (WO 91/16010).

Eisenberg teaches a composite skin equivalent comprising a porous cross-linked sponge matrix comprising living fibroblasts and a layer of non-porous collagen containing on its surface cultured keratinocyte cells. Both the fibroblasts and keratinocytes are obtained from skin samples (Abstract; page 5; page 6; first four paragraphs).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce as applied to claim 20 above, and further in view of Eisenberg (WO 91 16010).

A) Claim 39 is drawn to introducing living fibroblasts into the porous layer.

B) Teachings of Boyce are described above. Boyce does not teach to introducing living fibroblasts into the porous layer.

C) Eisenberg teaches a composite skin equivalent comprising a porous cross-linked sponge matrix comprising living fibroblasts and a layer of non-porous collagen containing on its surface cultured keratinocyte cells. Both the fibroblasts and keratinocytes are obtained from skin samples (Abstract; page 5; page 6; first four paragraphs).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have prepared the porous layer of the skin replacement of Boyce with fibroblasts, as shown by Eisenberg. The motivation to do so, expressly provided by Eisenberg, would have been that such a skin equivalent closely resembled human skin in structure, where the fibroblasts are in the dermis and keratinocytes in the epidermis.

11. No references were found teaching or suggesting claims 21 and 22, but they are rejected for other reasons.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone numbers for the organization

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where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS

February 19, 2002

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

2/19/02